



## Approval Sheet

Title of Thesis: Relationship Between Patient Acuity and Critical Care Noise

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## ABSTRACT

Title of Thesis: Relationship Between Patient Acuity and Critical Care Noise

Caryl J. Moulder, Master of Science, 1997

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This study examined noise levels at the bedside of critically ill patients and the relationship to severity of illness. It was based on the assumption that it is noisier around higher (sicker) acuity patients. Fifty subjects were selected using a non-probability systematic sampling method. Noise measurements were made twice on each subject, once at night and once during the day, for 30 minutes each. APACHE II Severity of Disease Classification and the Workload Management System for Nursing Patient Acuity Classification System were used to determine each subject's severity of illness. Pearson's product moment correlation using the average day/night noise levels and the severity of illness score resulted in a positive correlation for day noise ( $r = .35$ ,  $p < .01$ ) and night noise ( $r = .11$ ,  $p = .43$ ) but was not statistically significant due to the limited range of day noise (40.9 to 45 decibels) and night noise (39.3 to 40.9 decibels). The amount of noise measured at the patient's bedside did not increase with acuity levels. The average noise in this study was above the recommended level for sleep, 35 decibels at night and 40 decibels during the day (U.S. Environmental Protection Agency, 1974 & WHO, 1980). Further research into the harmful effects of noise in the severely ill and implementation of noise reduction measures in these patients seems warranted.

RELATIONSHIP BETWEEN PATIENT ACUITY  
AND CRITICAL CARE NOISE

by  
Caryl J. Moulder

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## TABLE OF CONTENTS

Chapter	Page
ACKNOWLEDGEMENT .....	iii
I. INTRODUCTION .....	1
A. Statement of the Problem .....	1
B. Purpose and Significance of the Study .....	3
C. Research Questions .....	4
D. Definition of Terms .....	5
E. Assumptions .....	6
F. Limitations .....	7
II. LITERATURE REVIEW .....	8
A. Noise Sources in the ICU .....	8
B. Noise Effects .....	12
C. Acuity/Patient Classification Systems .....	18
D. Summary .....	21
III. METHODOLOGY .....	23
A. Setting .....	23
B. Population .....	25
C. Sample .....	26
D. Instrumentation .....	27
1. Sound Level Measurements .....	27
2. Patient Acuity Classification .....	30
3. Pilot Testing .....	32



## TABLE OF CONTENTS

Chapter	Page
4. Data Collection Procedures .....	34
5. Institutional Consent and Protection of Human Subjects..	35
6. Study Design .....	36
IV. ANALYSIS OF DATA .....	37
A. Findings .....	37
1. Question One .....	37
2. Question Two .....	40
3. Question Three .....	41
4. Question Four .....	45
B. Summary .....	45
V. DISCUSSION, LIMITATIONS, CONCLUSIONS, IMPLICATIONS, AND RECOMMENDATIONS .....	51
A. Discussion .....	51
1. Question One .....	51
2. Question Two .....	52
3. Question Three .....	53
4. Question Four .....	54
B. Limitations .....	54
C. Conclusions .....	55
D. Implications .....	56
E. Recommendations .....	58

## TABLE OF CONTENTS

Chapter	Page
Appendix	
A: Data Collection Tool .....	59
B: APACHE II Severity of Disease Classification System.....	61
C: Workload Management System for Nursing.....	63
D: Letter of Exemption From the Institutional Review Board .....	66
REFERENCES .....	68

## LIST OF TABLES

Tables	Pages
1. Sample Characteristics .....	38
2. Paired t-test Results for Day/Night Noise Measurements .....	42
3. Day and Night LAV Readings by WMSN (Patient Acuity) Categories .....	43
4. Correlations Between Patient Acuity and Noise Levels .....	44
5. ANOVA of Noise Levels by WMSN Categories .....	44
6. Characteristics of Day High/Low Noise by Diagnosis and Gender .....	47
7. Characteristics of Night High/Low Noise by Diagnosis and Gender .....	48
8. Frequency of Room Occupancy to High/Low Noise .....	49
9. Characteristics of WMSN Categories by Diagnosis and Gender.....	49
10. Mean Number of Additional Pieces of Equipment per Patient by WMSN Categories .....	50
11. WMSN Points by Equipment Type .....	50
12. ANOVA of WMSN Categories and Patient's Age .....	50

## LIST OF FIGURES

Figures	Page
1. ICU Floor Plan .....	24
2. Sound Level Meter .....	28
3. Tabular Time History, Sample of Data .....	31

## Chapter 1

### INTRODUCTION

#### Statement of the Problem

Noise has become a major environmental problem and public health concern in most industrialized countries (Bowling & Edelman, 1987). Hospitals are noisy at times, despite the perception that they are a place for rest and recuperation. Redding, Hargest, and Minsky (1977) reported that the background noise in four intensive care units (ICUs) was as loud as the hospital cafeteria at noon.

The Environmental Protection Agency (1974) recommended that the noise levels in hospitals not exceed 45 decibels (dB) during the day and 35 dB at night. During a 24-hour period, average sound levels typically ranged from 55 to 65 dB, A-weighted (dBA), with peaks reaching 85 to 90 dBA (Aitken, 1982; Falk & Woods, 1973; & Seidlitz, 1981). Redding et al. (1977) reported that healthy individuals react negatively to noise at levels of 45-55 dB, but their reactions become vigorous at 65 dB.

Noise can have an adverse effect on people if it is excessive or is perceived as stressful. Discomfort occurs when environmental demands placed on an individual exceed that person's ability to cope. Critically ill patients exposed to 45-90 dB over a 24-hour period may develop physiologic and/or psychological responses to noise (Hilton, 1976; Noble, 1982).

Several detrimental effects of noise on critically ill patients have been documented: cardiovascular arousal (Carter, Hunyor, Crawford, Kelly, & Smith, 1994), sleep deprivation (Hilton, 1976; & Topf & Davis, 1993), "ICU psychosis" with delusions and hallucinations (Ballard, 1981; Hansell, 1984; & Helton, Gordon, & Nunnery, 1980), and increased pain perception (Minckley, 1968).

Critical care noise has been described as consisting of a moderate background noise with short episodes of higher level noise. The background noises include sounds made by ventilators, suction equipment, bubbling chest tubes, and pneumatic stocking devices. Short episodes of higher level noise include equipment alarms, patient coughing or talking, telephones ringing, and staff conversation. Several authors (Baker, 1992; Haslam, 1970; Whitfield, 1975; & Wilson, 1977) found that patients perceived that the most annoying source of hospital noise was from staff or visitors, sounds with frequent repetition (overhead pages), unnecessary sounds (radio and televisions), and loud sounds at night causing awakening.

As the severity of the patient's illness increases, noise normally increases. Rising acuity requires more nursing care and the use of more equipment. Verbal staff communication may also be more frequent due to increasing care requirements of the critically ill patient.

The critically ill patient's environment is noisy and possibly disruptive. Potentially harmful effects from excessive noise may delay the healing process or increase the severity of the illness. Therefore, excessively noisy patient

environments should be identified and efforts made to decrease this noise. Such efforts include turning the ringer down on the telephone, closing doors when possible, and encouraging quieter staff communications.

Noise generated within the environment and by staff was shown to disturb ICU patients sleep, on the average, every 20 minutes (Hilton, 1976). Southwell and Wistow (1995) reviewed the literature on patients' needs for sleep. Three themes emerged: "First, sleep disturbances have been widely documented; second, attempts to address this issue seem to have been largely ineffectual; and third, the importance of sleep appears to be underestimated in nursing theory and practice" (p. 1102).

The American Association of Critical Care Nurses (AACN) priorities for critical care nursing research specified the need for studies that explore effective methods to promote sleep and to prevent sleep deprivation (Lindquist, et al., 1993). This priority has been an ongoing concern for the AACN for twenty years.

#### Purpose and Significance of the Study

The purpose of this study was to replicate and validate Kotefka's research, (1992) which described noise levels occurring at the bedside of critically ill patients who had varying severity of illness in order to determine if noise levels increased as the severity of the patient's illness increased. A correlational, descriptive design was used in the previous study, which was conducted at a medical center in Texas. A sample of 50 was obtained (n=50) in an ICU and a step-down unit. Environmental noise was sampled and compared to two patient acuity systems. Consideration was given to each patient's nursing care and

equipment requirements since these are common sources of noise and easily measured for each patient (Kotefka, 1992).

While noise is consistently present in critical care areas, as of this date no studies, (known to this writer) except Kotefka's have been done to determine if there is a relationship between noise and patient acuity. In the past 6 years the critical care population has changed. Long-term critically ill patients are a growing segment of the critical care population (King, 1990). With the increase in severity of patient illnesses, the requirement for critical care beds, and the use of complex medical equipment at the patient bedside, the chance of increased noise and its potentially detrimental effects is evident.

If a relationship between the severity of illness and the amount of noise can be established, the information might assist nurses in the identification of patients prone to excessive noise exposure. Staff can then be more cautious with these patients and implement measures to decrease noise exposure, thus reducing some of the physiological and psychological effects associated with noise exposure.

### Research Questions

The following research questions were addressed in this and the previous study:

1. What are the noise levels encountered by adult critical care patients?
2. Is there a relationship between patient acuity level and the level of noise exposure?
3. What are the characteristics of the patients with the highest noise levels?



#### 4. What are the characteristics of the patients with the highest acuity levels?

##### Definition of Terms

The following terms are defined for use in this study:

Noise is a sound of any kind which is above levels recommended for a hospital that is confusing, indistinct, and/or perceived as undesirable. Technically speaking, it is any unwanted sound (Baker, 1992). Sound pressure or noise is measured in decibels. The decibel scale is logarithmic. Therefore a sound that increases by 10 dB becomes 10 times as intense and is subjectively perceived as being twice as loud. Sound is also a vibratory disturbance which is a frequency measured in cycles per second (Hz). The human organs of hearing are capable of detecting frequencies between 16 and 20,000 cycles per second (Hz). An "A" weighted scale is also used to approximate the frequency of the human ear by placing emphasis on the frequency range of 1000 to 6000 Hz. This measurement is called dBA. High frequency noise is thought to be more damaging than other frequencies (Kryter, 1984).

Critical Care Areas are areas in a hospital in which the patient who has life-threatening problems or is at risk for developing problems receives care. These areas are equipped to provide continuous, intensive, specialized, multi-organ support to the critically ill adult patient. Complex medical equipment is required for their care.

Patient Acuity is a term used to describe acuteness or severity of illness. Acuity systems are designed to gather information regarding the relative resource intensity of the patients, hence the list of tasks, procedures, and characteristics

that comprise the characteristics of patient classification systems (Shaha & Bush, 1996). In this study, the Acute Physiology and Chronic Health Evaluation (APACHE II) system and the Workload Management System for Nursing (WMSN) were used to determine patient acuity. A high positive correlation had been established between the two systems ( $r=.73$ ,  $p<.001$ ) (Kotefka, 1992). Both acuity systems were used to increase the applicability of these data to the general ICU population.

The APACHE II system is a severity of disease classification system in which basic physiologic principles are used to stratify acutely ill patients prognostically by risk of death (Knaus, Draper, Wagner, & Zimmerman, 1985). Physiological scores range between 0 - 71. A high positive correlation between APACHE II scores and in-hospital mortality provides evidence of the system's predictive ability (Knaus et al., 1985).

WMSN is a patient acuity classification system used to determine nursing care hour requirements in military hospitals and provide guidelines for effective allocation and utilization of nursing resources throughout all the hospitals (Reference Manual: WMNS, 1989). Patients scores range between 12 - 262, which are divided into six categories.

### Assumptions

The following were assumptions for the purpose of this study:

1. WMSN is a reliable and valid measure of nursing care requirements and patient acuity.

2. The APACHE II classification system is a reliable and valid measure of illness in the ICU environment.
3. Excessive noise levels can have negative effects on critically ill patients.
4. The decibel levels in the ICU are higher than the recommended levels for sleep for the ICU patient.

#### Limitations

The following limitations were identified:

1. The sample were selected from an adult critical care area with an open and closed unit design, thus limiting generalization to units with other designs.
2. Since APACHE II patient acuity calculations were made by the investigator, potential for bias exists though not intended.
3. Only four patients were monitored per day, thus all patients who would be exposed to excessive noise or would experience its harmful effects could not be identified.

## Chapter 2

### REVIEW OF LITERATURE

In this chapter the literature related to noise and acuity/patient classification systems in critical care areas is reviewed. Identified sources of noise, noise level measurements, patient perceptions of the noise, and related psychological and physiological effects are discussed.

Hospitals are commonly thought of by the public as a place for quiet, rest, and recuperation. Contrary to this belief, noise measurements show hospitals have loud and disruptive environments.

#### Noise Sources in the ICU

Noise levels in ICUs are usually high, because of the large numbers of patients and staff and great amount of equipment. Depending on the design of and crowding in the unit, noise levels may range from 45 to 90 decibels over a twenty-four hour period (Baker, 1992).

Woods and Falk (1974) measured noises generated by nursing care measures, staff/visitor conversations, and mechanical equipment in a seven-bed ICU and recovery room of a large teaching hospital. Noise was measured for a two month period during the hours of 7 a.m. and 9 p.m. Each measurement period was 1 to 2 hours in duration. The findings revealed that noise was generated mostly by people, not machinery. A high correlation ( $r=.63$ ) was found between noise at the patient's bedside and the number of staff present. The noise levels in two acute care units ranged from 50-76 dB(A). A "domino effect" was reported in the recovery room. If one patient cried out, nearby patients also began

to cry out, causing a chain reaction of ever-increasing noise. The authors suggested implementation of various noise reduction measures to include limiting staff conversations only to those necessary, positioning machinery as far away from the patient's head as possible, examining the necessity of leaving suction machines on continuously, using carpeting and draperies to absorb sound, consciously limiting unnecessary interaction with other patients and personnel in the vicinity of the patient during the hours of sleep, and keeping equipment with alarm amplifiers turned away from the patient's head.

Turner, King, and Craddock (1975) measured noise levels over one month in thirty four patient locations and four sites in the maintenance shops and mechanical equipment areas in a large suburban hospital. Noises were consistently well above sleep and speech interference levels in all areas. Coronary and medical-surgical ICUs, while expected to be among the quietest places in the hospital, were consistently above speech and sleep interference levels. Noises averaged just under 60 dB and just above 65 dB in the coronary and medical-surgical ICUs. Staff conversations were among the sounds that contributed to high noise readings. The other sounds that contributed to noise were the intercom system and the closing of doors and drawers on carts and cleaning equipment.

Sleep-disturbing factors were identified and the quality and quantity of sleep were documented by Hilton (1976). Ten patients in the respiratory ICU were studied. Five associates and the principal investigator collected data using continuous observations, recordings of sleep-disturbing factors, sleep stage

monitoring, and patient interviews. An electroencephalograph (EEG) machine and machines to record rapid eye movement (REM) and skeletal muscle tension were used to collect objective data continuously for 48 hours. One week after ICU transfer, subjective data were obtained through interviews with open-ended questions. Data about analgesic or sedation medication were also collected.

The sleep-disturbing factors identified in Hilton's (1976) study were mainly noises created by staff members and by the environment. Assessment and therapeutic procedures were also sleep disturbing. The quantity of sleep increased as sleep-disrupting factors were reduced. The quality of sleep was reported as poor among all subjects with a poor progression of sleep stages. Patients with analgesic or sedative medications experienced prolonged periods of stage 1/NREM sleep to the deprivation of all other sleep stages when noise levels were excessive. Behavioral changes such as restlessness, nightmares, and hallucinations were observed in 60% of the sample of ten.

Redding, Hargest, and Minsky (1977) described background noise in four units and found the noise comparable to the hospital's cafeteria at noon and only slightly less noisy than the boiler room. The ICU noise levels revealed consistently high levels of noise caused by equipment and staff. During this study, three physicians conferring generated 68 dB of noise. When three cardiac heart rate sensors were turned off, the background sound was reduced from 74dB to 61dB. Noise levels were also reported for different brands of nebulizers. The researchers demonstrated that equipment selection (i.e. buying quieter

equipment), lowering audible alarms, and a quieter staff can decrease noise levels.

Hilton (1985) described noise levels in various hospital acute care areas and patients' perceptions of these noises. A convenience sample of 25 subjects from four ICUs and two general care units in three hospitals were studied. Noise measurements were taken measuring equivalent continuous sound pressure levels (LEQ) and continuous decibel levels [dB(A)]. Two 3-hour observations were made to assess sources of noise. The two smaller ICUs' sound levels varied from 34.3-62.5 dB(A) LEQ, with the sound level remaining below 50 dB(A) LEQ 90% of the time. In the larger ICU/recovery room, the sound level remained above 50 dB(A) LEQ 24 hours a day and increased to 68.5 dB(A) LEQ during patient admissions. Sound levels dropped at night in four of the six units. Levels of talking by staff, patients, and visitors were 60 dB(A) or louder on all units. The increased noise levels on the larger units seemed related to the number of patients and lack of individual patient rooms.

Meyer-Falcke, Rack, Eichwede, and Jansing (1993) measured noise in three areas over seven days: the surgical intensive care unit (SICU), the anesthetic room, and the recovery room. In the SICU, sound level measurements were made one per hour for a period of 24 hours while patients were being weaned from mechanical ventilatory support. Equipment in use was also measured for its contribution to the noise levels. In the anesthetic room the measuring interval covered from the induction of anesthesia until the patient's transportation to the operating room. Measurements were taken in four rooms

and the composition of the staff using each room was examined. The recovery room was measured every 30 minutes during 8 hours of routine business. The SICU was never below 60dB, with a noise peak at 2200 hours due to the change of shift. The anesthetic rooms ranged from 51-72 dB. The quietest room was one in which only the head of the department worked. The recovery room fluctuated between 59.9-65.3 dB and the maximum noise was 81.4 - 93.3 d. No relationship were found between number of patients, type of anesthetic procedure used, and the noise level in the recovery room. Sound levels were low in emergency cases and high during routine work. This in itself was unusual, there is an assumption that an emergency case would be noisier. No explanation for this was given in this study. Noise was primarily from pulsating signals from monitoring and therapy apparatus.

Noise levels in the ICU are higher than those recommended for sleep. Staff and equipment have been documented to increase ICU noise, whether in the recovery room, surgery, or ICU.

### Noise Effects

Though noise levels in the critical care environment are not likely to cause hearing loss in the patient care setting, they can be harmful. Individuals' perception of noise is based upon their physical and psychological well being, past experience with similar sounds, and the perception of the type of sound, its loudness, and necessity (Harris, 1979). If annoying or stressful, noise can stimulate the autonomic nervous system through the auditory pathway and alter an individual's cardiovascular status, resulting in change in heart rate and rhythm,



myocardial oxygen consumption, and blood pressure (Falk & Woods, 1973).

Hospital noise has been associated with stress response symptoms, increased diastolic blood pressure and heart rate, sensory overload, sleep deprivation, and increased pain perception (Griffin, 1992).

In a descriptive study, Minckley (1968) found a relationship between the amount of noise and frequency of pain medication administration in the recovery room. All patients entering the recovery room (n=644) during a randomly selected 5 day period were observed. The frequency and times of pain medication administration were collected from the patient charts and noise levels were recorded. Significantly greater amounts of pain medication were administered during periods of high noise. In fact, 75% of the medication was administered during increased noise levels. This study was designed to look at overall noise levels and pain medication frequency in the recovery room, the inference can be made that an individual patient brought to the ICU directly from surgery might be exposed to less noise.

Baker (1992) proposed three questions to explore the relationship between sources and levels of noise and heart rate response: 1) What are levels of noise in the ICU during 6 evening hours? 2) What is the change in heart rate of patients in response to different noise levels in the ICU? 3) What is the change in heart rate of patients in response to different sources of noise in the ICU? Her sample consisted of 28 hospitalized patients in private rooms located on the outer three sides of the ICU; each room had a window. Data were collected within 5 hours of admission to the unit. Noise in dB and heart rate were recorded continuously and

simultaneously for 6 hours. Noise sources were identified and categorized into three groups: 1) talking inside the room; 2) talking outside the room; 3) nontalking noise: observed patterns from alarms, phones, equipment, and computer printers, etc.; 4) ambient noise: steady state noise remaining essentially constant. The grand mean sound pressure level (SPL) across 6 hours of data collection was 60.5dB(A) - 62.4 dB(A). The loudest hour was during shift change.

During a noise episode, when an increase in sound from 3 to 6 dB or greater occurred, (average number of episodes was 23 per subject) the patient experienced an increase of 2 to 12 bpm for each 6dB increase in noise. While changes in mean heart rate and decibel level among all subjects in the study were clinically small, there was a significant increase in the heart rate in the majority of subjects in response to talking inside the room.

The effects of noise on sleep are not well understood. It appears that noise can prevent a person from going to sleep or can awaken one from sleep if it is of sufficient intensity, has important meaning, or is of unusual character (Kryter, 1972). Sleep, a primary requisite of healing, is sometimes lost in the ICU environment (Evans & French, 1995).

Many of the studies (Helton, Gordon, & Nunnery, 1980; Hilton, 1976; Falk & Woods, 1973; & Meyer, et. al, 1993) done in the critical care environment examined the relationships between noise and sleep in the ICU. Falk and Woods (1973) found that noise, especially when occurring during sleep, produced marked physiological changes in the endocrine and cardiovascular systems. This included an increased pituitary release of adenocorticotrophic hormone (ACTH).

The release of ACTH stimulated adrenocortical activity. Noise also effects the adrenal medulla, increasing urinary excretion of epinephrine and norepinephrine, peripheral vasoconstriction, increased heart rates, and arrhythmias.

Thiessen (1978) determined that when mean environmental noise levels exceeded 50 dB(A), the chance that a patient would awaken was 10-20%. As sound levels increased, the chance that patients would awaken increased.

Helton, Gordon, and Nunnery (1980) examined the correlation between sleep deprivation and the "ICU syndrome". Data were collected from 62 patients during their first 5 days in an ICU. Two assessment scales were used by nurses: mental status and a sleep interruption checklist. The researchers found that patterns of sleep interruption corresponded with severity of illness. In the patients classified as sleep deprived, 33% demonstrated a deterioration in the mental status assessment scale. Surgical patients complained of an inability to sleep more often than medical patients. Reliability and validity were not addressed in this study for the tools used: however, one limitation addressed was the sleep interruption checklist. Since the nurses were instructed to use the checklist prior to performing a specific nursing activity, they may have decreased the frequency of interruptions, accounting for more uninterrupted periods of sleep.

Meyer, Eveloff, Bauer, Schwarts, Hill, and Millman (1994) examined sleep deprivation in a 720 bed university hospital in a three-bed medical ICU, a three-bed recovery room, a single recovery room, and a private room on a general floor. They postulated that light, sound, and interruption levels in a weaning unit are major factors in sleep disorders and possibly cause circadian rhythm

disturbances. Sound levels, recorded for each minute of every day, were 82.6-83.6 dB. The mean peak level in private rooms was lower than other areas but was still quite high at 75.5 dB. When separated by time of day the night measurements decreased 2 - 4 dB(A) in all settings. The reasons for the higher sound levels in this institution were unclear. It may have been associated with the positioning of the sound level meter, the fact that the rooms were not constructed to minimize noise reflection or intensity, or that the levels measured were actually a true reflection of patient exposure. The sound and interruption levels were severely disruptive and the normal sleep-wake cycle in exposed patients was not maintained.

Somewhat more convincing data in support of causal relationship between hospital sounds and disrupted sleep were collected in laboratory experiments. Topf and Davis (1993) looked at noise and rapid eye movement (REM). Their study was conducted in a sleep laboratory and the 70 subjects were paid. The subjects were randomly assigned to a quiet (control) or noise group while attempting to sleep overnight in the laboratory. Noise-condition subjects heard an audiotape recording of critical care unit nighttime sounds. Sleep stages were measured using polysommography; REM sleep was measured using an electroculograph; chin tone (EMG) was used to distinguish REM sleep from stage 1/NREM; and an EEG measured brain activity. Subjects in the noise condition had less and shorter duration REM sleep than those in the control group.

The results of this study supported the hypothesis that noise-condition subjects would exhibit poorer REM sleep compared with the quiet-condition

subjects. Noise-conditioned subjects had less REM activity and a shorter REM period duration. There were also some unexpected findings. Both the noise and quiet subjects exhibited features of REM sleep that were different from adult sleep norms (i.e. it took longer to reach stage-REM). This may have been adaptation to the sleep laboratory. A recommendation from this study concerns the design of a critical care units. Acoustic features that reduce sound levels should be incorporated in planning and design. Limitations to this study included the use of healthy subjects and the laboratory environment, which limits generalization of the results to patients.

Carter, Hunyor, Crawford, Kelly, and Smith (1994) also conducted a sleep study in a laboratory. Nine adults with documented cardiac arrhythmia were studied during four nonconsecutive nights. A sleep polygraph and single-channel electrocardiogram were recorded continuously throughout each night. The subjects had one night to familiarize themselves with the laboratory. They were then exposed to either 50 calibrated aircraft or truck noise events for two nights. One other night was noise free. Sleep stage intervals, sleep stage changes, premature ventricular contractions (PVC), and overnight urinary catecholamines were measured. It was found that noise increased the likelihood of arousal responses to the same extent in all sleep stages. Four subjects showed frequent PVCs during the experiment. The PVCs were related to slow-wave sleep stages and not noise. Urinary catecholamines did not differ between the quiet and noise night. This study raised questions concerning noise and PVCs: Are patients with complex arrhythmias more susceptible to noise during sleep?; Can sudden onset

sounds from alarms induce cardiac arrhythmias?; To what extent do these effects, if any, depend on sleep stage noise onset?

Southwell and Wistow (1995) reviewed the literature on patients needs and sleep. Three themes emerged: "First, sleep disturbances have been widely documented; second, attempts to address this issue seem to have been largely ineffectual; and third, the importance of sleep appears to be underestimated in nursing theory and practice" (p. 1102).

Kotefka's (1992) study found a positive relationship between patient acuity and noise in a large university's ICU. Fifty subjects were randomly selected. Two noise levels were monitored on each subject, once at night and once during the day, for 30 minutes each time. The APACHE II Severity of Disease Classification and Workload Management System for Nursing for Nursing Patient Acuity Classification System were used to determine each subject's severity of illness. A Pearson's product-moment correlation using average noise level and severity of illness score resulted in a positive correlation ( $r = 0.62$ ,  $p < .001$ ). The amount of noise measured at the patient's bedside increased with acuity level calculated for each patient. This was the only study, to the knowledge of this investigator, that links patient acuity and severity of illness.

#### Acuity/Patient Classification Systems

Historically, prospective patient classification systems have been used to justify nursing resource allocation on a day-to-day, shift-to-shift basis to determine the anticipated care needs of the patient and staffing resources (Alward, 1983; Edwardson & Giovanetti, 1983; Giovanetti, 1979; & Hlusko, 1996).

Hlusko (1996) examined retrospective classification scores to determine whether actual care delivered differed significantly from the score obtained from a prospective classification system. Nursing administration believed that their prospective classification was not an accurate reflection of the resources needed and used within the hospital. Analysis of variance indicated significant differences between prospective and retrospective analysis for the majority of categories by unit. These questions arose from this study: "How should patient classification data be used?; Is prospective data the correct data to use to allocate staffing, or should staffing budget be based on retrospective data?; and Are both types of classification useful to the nurse administrator?"(p. 44).

Shaha and Bush (1996) describe the main purpose of an acuity system as a way to categorize patients into classes meant to represent their care needs. Caregivers complete a form tallying the tasks, procedures, and characteristics associated with each patient. This then leads to a mathematical formula to predict the amount of nursing care needed for each patient. Acuity has been increasingly used in an effort to control the rising cost of patient care through tools designed to dictate appropriate staffing levels.

Workload Management System for Nursing (WMSN) has been used by the United States Air Force since 1989. The total hours for direct and indirect care required for each patient are computed from critical indicators and placed in one of six categories. The system provides measurable information about a patient's nursing care hour requirements, but it also assists in determining staffing requirements and mix for the unit and the hospital (Reference Manual WMSN,

1989). Counter-related validity was  $r = .98$  and criterion-related validity ranged from  $r = .87$  to  $r = .99$  in a four phase study by Sherrod (1983). Interrater reliability for critical care was .91 and internal consistency was .93.

Wagner, Knaus, and Draper (1983) evaluated the Acute Physiological and Chronic Health Evaluation (APACHE) tool, a severity of illness scale. At the time of the study, APACHE was a new approach to measure the severity of acute illness for a wide range of hospitalized patients. This scale used data from all seven of the body's major organ systems, thereby increasing the number of diagnoses for which it is potentially useful. The sample size was 833 nonoperative, unscheduled, emergency admissions to the George Washington University Medical Center ICU. The first part of the tool was the Acute Physiology Score (APS), designed to measure the acute severity of illness; it consisted of a weighted sum of each of the 33 potential physiologic measurements obtained from the patient's clinical record. A weight ranging from 0 to 4 is assigned for each recorded measurement to reflect "how sick" the patient is. For example, a heart rate between 70 to 110 is assigned a weight of 0, but a heart rate over 180 or under 40 is assigned a weight of 4. These 33 potential measurements reflected the degree of derangement of all the body's seven major physiologic systems. The other part of APACHE was the patient's chronic or preadmission health status, measured in four types or categories; good health, mild to moderate limitations, serious limitations, and severe restrictions of activity.

A strong, stable, and highly significant relationship was found between the APS of APACHE and hospital survival for groups of nonoperative ICU



admissions. The independent impact of age was a significant indicator on a person's capacity to recover from serious injury. APACHE classifications were not entirely independent of therapy. Prompt medical action might rapidly correct abnormal physiologic measures and could reduce their progression. The researchers planned to do multi-institutional validation studies.

Knaus, et. al. (1985) reported the results of a nationwide effort to validate APACHE II. This severity of disease classification system used basic physiological principles to stratify ill patients. APACHE II was a revised version of the prototype system, APACHE. The original system used 33 weighted variables, APACHE II used twelve variables. Infrequently measured physiologic variables such as serum osmolarity, lactic acid, and skin testing for anergy were deleted, as were potentially redundant variables. Thus serum BUN was replaced by serum creatinine value and serum pH was retained in preference to bicarbonate. Thirteen hospitals were used to validate this tool. The test period was from 1979 to 1981 and a total of 5815 intensive care admissions were examined. APACHE II was found to be a reliable and useful means of classifying ICU patients. Unlike other patient acuity systems, APACHE II is not task oriented; it is physiologic in nature.

### Summary

Excessive noise is known to cause not only hearing loss, but also stress, sleep deprivation, sensory overload, "ICU syndrome", and a heightened response to pain. The endocrine response to stress can also result in an increase in urinary excretion of epinephrine and norepinephrine, peripheral vasoconstriction,

increased heart rates, and arrhythmias. These effects in an already compromised critical care patient could delay healing and recuperation or even worsen the disease process.

Acuity/patient classification systems have been used to justify nursing allocation of resources. Another way to define acuity is a classification system organized into care categories and predicting care needs. WMSN groups patients into categories based on direct and indirect care required, thus, indicating staffing needs. APACHE II, on the other hand, measures the patient's physiologic characteristics and preadmission status, not nursing care needed. Both of these systems are beneficial to the nursing community and used jointly provide an indication of a patient's acuity. High acuity, whether assessed on a prospective, retrospective or physiological basis may help to identify those patients at risk for exposure to high levels of noise so that appropriate interventions can be taken to reduce potential detrimental effects of excess noise.

## Chapter 3

### METHODOLOGY

This study of noise levels at the bedsides of critically ill patients replicated as closely as possible Kotefka's (1992) study. The previous study, conducted at a large university ICU setting, included private ICU and step-down beds. A correlational, descriptive design was used. The setting, population, sample, instrumentation, procedure, protection of human subjects, study design, and the statistical analysis used in this study are discussed in this chapter.

#### Setting

The setting for this study differed from the original, in that it was conducted at a military hospital with a combined open bay and closed bed floor plan. Data were collected in a military hospital in the greater Washington DC area in a 10 bed intensive care unit (ICU) which had 5 individual closed rooms and 5 bay beds (Figure 1). Two closed bed were not used; Bed H was set up as a training area and Bed G was inhabited by a long term patient.

Because noise levels vary in different settings, a detailed description of the environment in which the study occurred is necessary. The ICU was located on the second floor, adjacent to the telemetry unit. The rooms and bay were located around a centralized nursing station; centralized monitoring occurs at the entrance of the ICU. The closed rooms are cinder block design with sliding glass doors. The bay beds are separated by curtains and the floor is tiled throughout the ICU. Measures to reduce noise consisted of acoustic tile on the ceiling, lined drapes, and glass doors on the closed rooms. The individual rooms vary in size

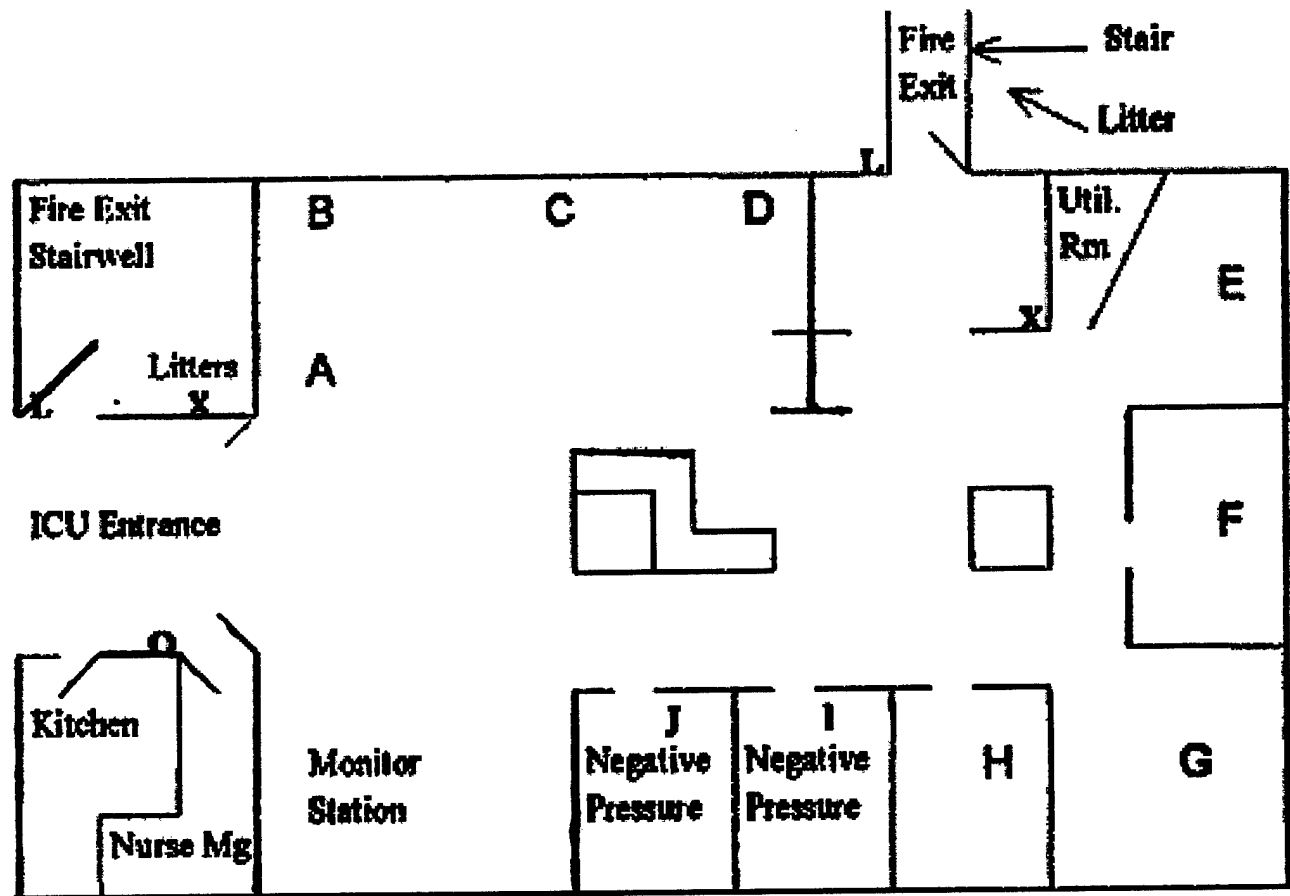


Figure 1: ICU Floor Plan

but do not vary in the standardized equipment at the bedside. The open bay beds have the same standardized equipment as do the individual rooms.

The staff change shifts at 0600 and 1800 hours. The team leader comes in fifteen minutes before the staff to make patient assignments. Approximately six nursing personnel work in the ICU at any one time. Nursing and physician reports are customarily given immediately outside the patient's room or at the central nursing station. The patients' doors are closed for report, but the patients in the bay do not have doors, only curtains to separate the cubicles. Physician presence varies with the time of day and the severity of illness of the patient. The ICU staff attending physician, as well as vascular, general surgery, and cardiology physicians normally make rounds every morning between 0630 and 1100 hours. From one to as many as 12 people can be at a patient's bedside during this time. After rounds, the physicians stay on the unit as needed and normally see patients again in the late afternoon. One respiratory therapist is assigned to the ICU and is included in morning rounds.

#### Population

The ICU capacity is 10 beds; the average daily occupancy is four to six patients. The ICU population consists primarily of patients 18 years of age and older who have medical or surgical intensive care needs. These include the following types of patients: ventilator dependent, myocardial infarctions, GI bleeds, post-operative vascular surgeries, thoracotomies, and single system trauma. The average length of stay is 1 to 60 days and occasionally patients awaiting long term placement stay longer.

### Sample

All patients in the ICU were considered for this study. This study utilized Kotefka's three exclusion criteria (1992):

- (a) any patient who was not going to be present on the unit during both of the subsequent night and day noise measurement periods,
- (b) any patient whose anxiety increased when the noise meter was placed at the bedside despite explanation of its use and purpose,
- (c) any confused or combative patient who was not restrained. In this circumstance, the potential for displacement of the noise level dosimeter's microphone, distortion of the noise level measurements, or damage to the equipment from the patient was deemed too great (p. 30).

A non-probability, systematic sampling method was used for subject selection and WMSN was used to determine patient acuity. Each patient was classified when admitted to the facility and again every 24 hours. On any given day, the ICU's two highest and two lowest acuity patients were selected for data collection if they did not meet the exclusion criteria. No patient was used twice in a single ICU stay. Data were collected Tuesday through Saturday. Biomedical support was not available on the weekends or on federal holidays and the sound level meter (SLM) could not be downloaded or reprogrammed without their computer. Data collection resumed at 0100am Tuesday after the SLM had been reprogrammed from the Saturday collection.

The planned sample size (n) for this study was 68 patients as determined from a power table for the significance of a product moment correlation (Cohen, 1988). A one-tailed t-test criterion was used to predict a positive direction of association, a power of .80, and a medium effect size (r) of .30. Medium effect is defined as the "degree of relationship that would be perceptible to the naked eye of a reasonably sensitive observer" (Cohen, 1988, p. 81). The data collection period was planned to continue until 68 patients were measured or until 25 January 1997. Data collection was finished on 31 January 1997 and  $n = 50$ .

#### Instrumentation

Four instruments were used in this study. Noise levels were measured with a sound level meter (SLM). Patient acuity was determined by two methods: the APACHE II Severity of Disease Scoring System and the Workload Management System for Nursing Patient Acuity Worksheet. Each patient's demographic data and the resultant information from the other three instruments were recorded on a data collection form developed by the investigator (Appendix A). Kotefka's tool utilized different headings for SLM and these did not conform to the reading from the Metrosonic db-3100.

#### Sound Level Measurement

The instrument used to measure sound in this study differed from that used in the previous study but it was capable of collecting noise data in the same way as did the previous instrument. The instrument used by Kotefka is not available locally. The instrument used was a db-3100 Metrologger by Metrosonics (Figure 2). It is a small, hand-size, battery operated device which contained a

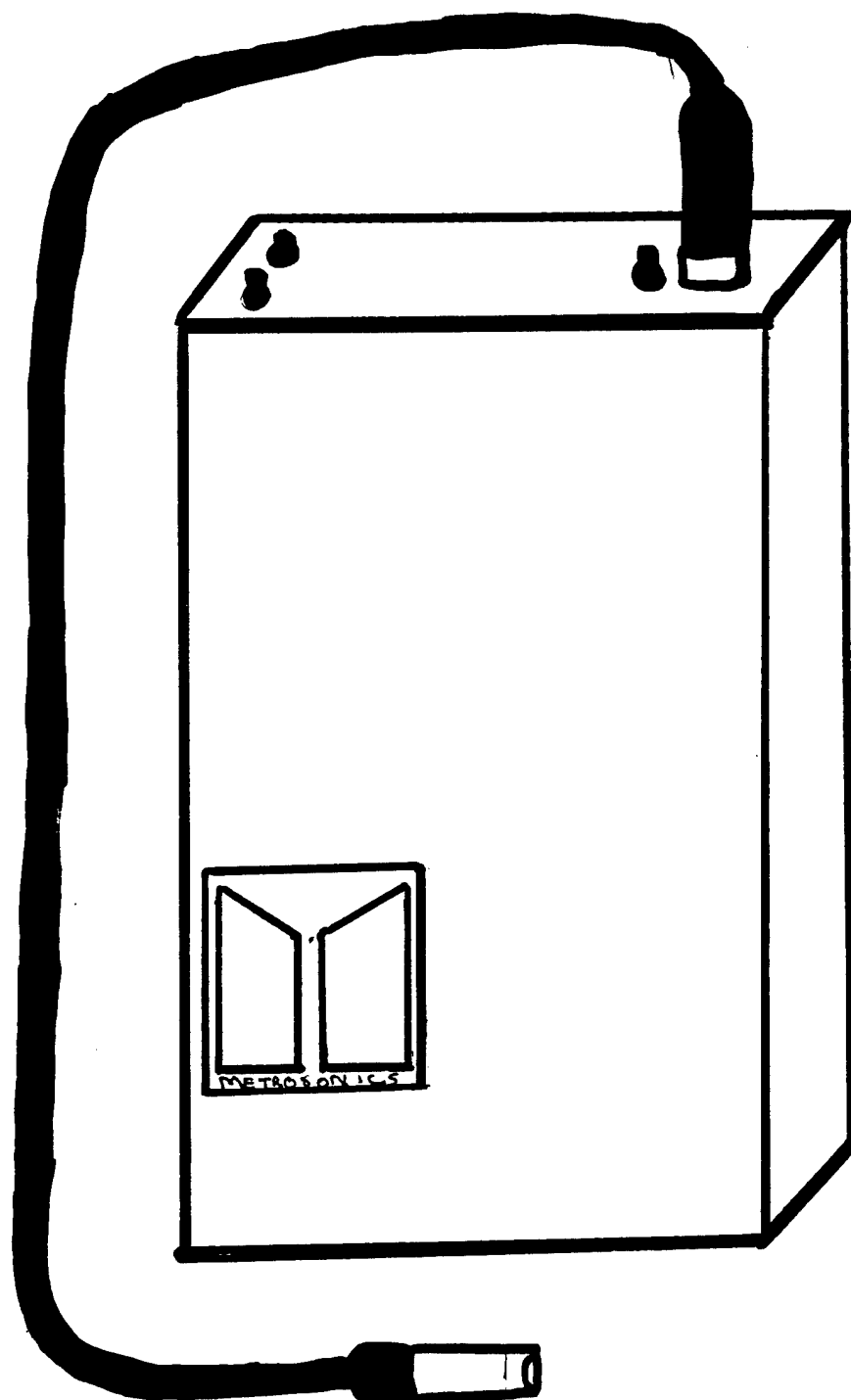


Figure 2: Metrosonic 3100 dB Sound Level Monitor



universal dosimeter, an integrating/averaging and true peak sound level meter and a time history monitor. As shown in Figure 2, it was housed in a rugged, light weight, water-tight aluminum case and can withstand environmental and industrial usage (Metrosonics Owner's Manual). Programming changes can be accomplished by using the ms-935P Programming Disk and an IBM compatible computer. Fully formatted reports were sent directly to a printer from the db-3100. This SLM and accompanying computer software is approved by the Occupation and Health Administration (OSHA) and the Environmental Protection Agency to measure and record environmental noise and is also used to measure environmental noise in machine and airport facilities.

The SLM was programmed with predetermined settings. The db-3100 range of measurement is 40 dB to 140 dB (Owner's Manual). Since sound level meters normally measure continuous noise which has no significant fluctuations, adjustments were made for variations in noises that occur in a critical care unit. The detector was set to SLOW response to permit a steady reading when rapid variations in sound levels occurred (Tempest, 1985). An A-weighted scale [dB(A)] was also used to more closely approximate loudness as heard by the human ear. For measurement of non-steady-state noise, the exchange rate was set to 3 dB. The resultant Equivalent Level (LEQ) approximates the value of a steady sound for an elapsed period of time. For this study data were recorded every minute. The db-3100 averages noise level over an elapsed period of time, i.e. every minute. The SLM was calibrated to +102.0 dB before each daily data collection period with a cl-304/304A/304B Acoustical Calibrator by Metrosonics. Two sound

meters were available from the military base's Biomedical department, one for the day measurement and one for the night time measurement. One SLM was preprogrammed to turn on at 0100am and the second SLM at 0600am. Since the SLM can only be programmed to turn on one time without being downloaded, two SLMs were used for data collection. The noise meters were calibrated daily and the data were printed onto paper at Biomedical Department office by an assigned technician.

As shown in Figure 3, six columns were recorded on each computer printout. The first was placement number followed by time. Sound pressure levels (SPL) were reflected in several ways. The average SPL per minute was recorded as the LAV. The maximum SPL detected since the last reading was recorded as LMX. The peak impulse reading that occurred since the last measurement is the LPK. The symbols L1, and L2 indicate the SPL that is exceeded 'n' percent of the time. For example, if L1 is 41.0, then the SPL is greater than 41.0 only 10% of the time. Likewise, L2 means that 99.9% of the SPLs are above this point.

#### Patient Acuity Classification

The APACHE II Severity of Disease Scoring System is used by hospitals nationwide to describe severity of illness and as an indicator of patient outcome (Appendix B). It was used to determine patient acuity during this study. During the previous study (Kotefka, 1992) scores fluctuated with age. Age is one of the physiological criteria of the APACHE II.

The WMSN is a patient classification system developed by the military and used exclusively in military hospitals (Appendix C). The total hours of direct

TABULAR TIME HISTORY  
 # OF PERIODS: 90 MODE: CONTINUOUS  
 PERIOD LENGTH: 0:0100  
 TIME HISTORY CUTOFF: 80Db  
 Ln (1):10% Ln(2): 99.9%

Date 1/31/97

INT	TIME	Lav	Lmx	Lpk	L1	L2
1	6:00	41.1	70.5	UNR	66	57
2	6:01	41.1	66.5	UNR	64	56
3	6:02	41.1	76.3	UNR	61	54
4	6:03	41.1	65.9	UNR	64	55
5	6:04	41.1	67.6	UNR	64	55
6	6:05	41.1	66.7	UNR	63	55
7	6:07	91.3	108.2	OVR	62	56
8	6:08	41.1	66.7	UNR	84	54
9	6:09	41.1	61.6	UNR	57	53
10	6:10	41.1	63.9	UNR	57	54
11	6:11	41.1	69.5	UNR	59	54
12	6:12	41.1	76.1	UNR	59	53
13	6:13	41.1	69.7	UNR	68	54
14	6:14	41.1	72.3	UNR	61	54
15	6:15	41.1	73.6	UNR	63	54
16	6:16	41.1	63.9	UNR	67	54

and indirect nursing care required for each patient are computed from critical indicators and placed in a category from I to VI. The system has several functions. Not only does WMSN provide measurable information about patients' nursing care requirements, it also assists in determining staff requirements and mix for the unit and the hospital (Reference Manual WMSN, 1989). Content-related validity was  $r = .98$  and criterion-related validity ranged from  $r = .87$  to  $r = .99$  in a four phase study by Sherrod (1983). Interrater reliability for critical care was .91 and internal consistency was .93. WMSN is the acuity system utilized by the facility where the study was conducted. WMSN classification is done at the time of admission and updated daily by the patient's primary nurse.

Kotefka (1992) correlated the APACHE II scores, WMSN scores, and WMSN categories using a Pearson's  $r$ . The APACHE II scores had a correlation ( $r$ ) of .73 with the WMSN scores and .70 with WMSN categories ( $p < .001$ ,  $n = 50$ ). Both acuity classification systems were used to increase overall generalization to ICU populations.

### Pilot Testing

Pilot testing was conducted once IRB approval had been granted. The reasons for pilot testing were three fold. First, Kotefka (1992) reported difficulty with staff compliance and difficulty with the SLM position at the patient bedside during the data collection period. In order to minimize these difficulties, this investigator remained on the unit during data collection. The SLM was tested at the bedside of one patient to determine whether the instrument would pick up

environmental noise. The SLM demonstrated a LMX of 108 dB(A) and a LAV of 69 dB(A) over one hour.

Prior to data collection, information was provided to the nursing staff regarding the purpose of the study, the procedure for data collection, the desired microphone placement with some precautions for use, and capabilities of the noise meter. Nursing staff questions were answered throughout the data collection period. The outcome of the study and recommendations were presented in Grand Rounds for the entire hospital staff at the completion of the project.

The second reason was to establish collection times. Kotefka (1992) determined that the highest levels of noise were from 0800-1100 hours, and the lowest from 0100-0430 hours daily. To confirm these times an initial pilot test was run for twenty-four hours for two days (i. e. 48 hours). A graph was printed out to confirm the peak times for noise in the ICU and the data collection times were established. This study's times differed slightly from those of the previous study. The quietest time was from 0100am to 0400am and the noisiest from 0600am to 0900am and again from 1700pm to 2000pm. The noisy times correlated to change of shift and patient report.

The third reason for pilot testing was to determine if and how the equipment worked. During pilot testing, it was determined that the SLM would only run eight hours.

Prior to the pilot test the SLM was calibrated to 102 dB by the Biomedical department. The SLM was suspended from an IV pole by the clip on the back of

the SLM's case. The pole was placed in a subject's room and the microphone was positioned 8-12 inches from the patient's head at ear level.

#### Data Collection Procedures

The Metrosonic dB-3100 was programmed with predetermined parameters and set to record average noise levels every minute during the daily collection period 0100 to 0400am and 0600 to 0900am. These two times were identified during the pilot test as the quietest and loudest time in the ICU. The noisier periods had the same LAV and LMX. Data were collected over 30 minutes twice a day on each patient. Each SLM was programmed to run for three hours during the two collection periods. The data collection time for four patients is two hours, the extra time enabled the investigator to move and adjust the microphone for each patient. The extra time also provided leeway in the event that the SLM could not be moved due to patient circumstances i. e. a cardiac arrest. The plan to support the dB-3100 from an IV pole to make transporting from room to room easier worked. The team leader assisted the investigator in determining which patients were monitored. The two highest acuity patients each were monitored for 30 minutes a piece and then the monitor was moved to two low acuity patients' bedsides. The patient's registration number, the time the data collection started and ended, and the WMSN category were recorded on the data collection tool. Demographic information included gender, age, ethnicity, and diagnosis of the patient. The researcher then determined the APACHE II scores for each patient from the patient's chart. The amount and type of equipment in use in each patient's room was also recorded.

The day data collection period started at 0600am. The same patients from the previous night were measured. At the end of the daily collection period the investigator took the SLMs to the Biomedical department to be downloaded. The Biomedical technician calibrated, printed the data, and reprogrammed the monitors. The investigator then had the SLMs for the next collection period.

Problems during data collection were a low patient census and high turnover rate. The ICU did not always have new patients to be monitored. The limited weekly time frame of Tuesday to Saturday also resulted in fewer patients to be monitored. Data collection was done for six weeks, with the exceptions of holidays and weekends. Data were collected from fifty subjects, the same number that Kotefka had utilized.

#### Institutional Consent and Protection of Human Subjects

Permission to conduct this study, specifically to review the patient's chart and place the noise dosimeter at the patient's bedside, was obtained from the institution from which the sample was selected. Exemption status was granted from the Institutional Review Board at the University of Maryland at Baltimore and through the Institutional Review Board at Malcolm Grow Hospital. Support was obtained from the ICU nurse manager and the Medical Director of the ICU. No manipulation or changes to the existing WMSN score occurred during the data collection of this study. Data were compared from the paired day/night observations. To avoid duplication of selected patients, a list of names and code numbers was maintained by the investigator until completion of data collection (when the patients register number and name were removed from the data).

### Study Design

A correlational, descriptive design was used to determine if noise level at the bedside of a critically ill patient is related to the severity of illness. A systematic, non-probability sampling technique was used to decrease the potential for researcher selection bias.

### Data Analysis

Duplication of the statistical analysis from Kotefka's (1993) study was conducted using descriptive statistics to summarize demographic data, to describe the noise levels and acuity scores, and to describe the amount and frequency of equipment used. A paired t-test was used to determine if there was a difference between noise levels during the night and day measurement periods. The overall and individual average noise level measurements were correlated with the calculated patient acuity scores. A Pearson's Product Correlation was used to test and predict relationships between noise levels, patient acuity, and noise source. A one-way ANOVA was used to determine if noise varied between patient acuity and day and night LAVs.



## Chapter 4

### ANALYSIS OF DATA

A description of the sample characteristic, as well as a description of the findings in relation to the posed research questions are presented in this chapter. Noise levels were measured on a total of 50 ICU patients.

The sample included 30 (60%) men and 20 (40%) women. Their ages ranged from 40 to 83 with a mean age at 65.5 years ( $SD = 9.38$ ).

The four open bay beds were used by 38 patients and the four closed beds were used by 22 patients for a total of fifty patients (see Table 1). The significance of patient placement and noise level is discussed in the findings.

The population fell into one of three WMSN categories, III to VI, with a mean category of IV ( $SD = .72$ ). The APACHE II scores ranged from 2 to 25 with a mean score of 10.50 ( $SD = 4.59$ ).

### Findings

Data analyzed included noise level, patient acuity scores, and the amount and type of equipment in use. Each research question is addressed using the 50 paired observations.

#### Question One

The first research question was: "What are the noise levels encountered by adult critical care patients?" Descriptive statistics were used to characterize the noise levels for each patient. The day and night LAV measurements were used to determine each patient's overall noise exposure. The average day noise level ranged from 40.90dB to 45 dB with a mean of 41.27 dB ( $SD = .96$ ). The

Table 1

Sample Characteristics

Age categories	f	%
40 - 50	4	8
50-59	7	14
60-69	22	44
70-79	15	30
80 - 83	2	4
<hr/>		
Diagnoses	f	%
Cardiovascular	28	57
Respiratory	8	16
Gastrointestinal	5	10
Neurological	1	2
Renal	1	2
Surgery/Postoperative	6	12
Other	1	2
Total	50	100

(table continues)

Table 1

Sample Characteristics

Bed Breakdown	f	%
A (Bay Bed)	7	14
B (Bay Bed)	8	16
C (Bay Bed)	8	16
D (Bay Bed)	5	10
E (Private Bed)	9	18
F (Private Bed)	2	4
I (Private Bed)	6	12
J (Private Bed)	5	10
Total	50	100
<u>WMSN Categories</u>		
III (32-63)	6	12
IV (64-95)	28	56
V (96-145)	14	28
VI (146-262)	2	4
Total	50	100

average night noise level ranged from 39.3 dB to 40.90 dB with a mean of 39.75 dB (SD = .49).

A paired-sample t-test was performed to determine if noise levels varied between night and day collection periods for each patient. The findings approach significance between the two measurement periods with a  $p < .001$  (see Table 2). According to the mean measurements, night noises were less than the day noises, average night noise was 39.74dB compared to average day noise of 41.27dB.

### Question Two

The second question was: "Is there a relationship between patient acuity level and the level of noise exposure?" Day/night LAV reading were examined by WMSN categories. The mean day LAV reading was similar for all WMSN categories. The mean night LAV was also similar for all WMSN categories (see Table 3). In order to determine the relationship between patient acuity and noise at the bedside, a Pearson's product moment correlation coefficient ( $r$ ) was calculated to describe the relationship among the variables (APACHE II scores, WMSN points, WMSN categories, average day and night noise, and maximum day and night noise) (see Table 4). Interestingly, all demonstrated a positive relationship but were not statistically significant for each correlation, day and night ( $r = .35$  &  $r = .11$ ,  $p < .01$ ). The correlation for WMSN number and average day noise approached significance at  $p = .079$ . The three acuity measures were significantly correlated at  $p = .002$ , indicating positive validity of the acuity measures. The APACHE II scores indicated a homogeneous sample. The noise

levels for each patient did not increase significantly above the WMSN category V. The majority of the patients were in the level IV category.

To test if noise levels varied with patient acuity categories, a one-way ANOVA was performed between day and night LAVs and WMSN categories. No two groups were statistically significant (see Table 5).

### Question Three

The third question was: "What are the characteristics of the patients with the highest noise levels?" Descriptive statistics were used to characterize the patients' diagnoses and their presence in the low or high noise group. The means of the day and night LAV were used to split the LAV into low and high measurements (Day LAV mean 41.27, Night LAV mean 39.75). The range on night LAV was 39 to 40.68, thus, there was not a high and low. Due to the night LAV range, the day and night LMX were also included. The LMX figure is a one time increase during the data collection period. It is not constant noise. One patient in the cardiovascular group, three respiratory patients, and two postoperative patients were in the high noise group. Patient gender was also divided into high and low noise groups for day and night to see if gender is related to higher noise levels (see Table 6 & 7). Interestingly, only two patients in the bay fell into the high noise level group during the day compared to four in private beds four patients (more patients occupied the bay). The night LAV did not vary (see Table 8).

Table 2

Paired t-test Results for Day/Night Noise Level Measurements

LAV	n	Mean	Standard deviation	r	t
Day LAV	50	41.2700	.957		
Night LAV	50	39.7480	5.755		
Paired results	50	1.522	5.862	.072*	1.84

\* = statistically significant  $p < .001$ .

Table 3

Day LAV Reading by WMSN (Patient Acuity) Categories

WMSN Categories (points)	Mean LAV	Minimum	Maximum	Standard deviation	Cases
Cat III (32-63)	41.05	41	41.1	.0548	6
Cat IV (64-95)	41.15	40.9	45	.7599	28
Cat V (96-145)	41.61	40.9	45	1.4384	14
Cat VI (146-262)	41.2	41.1	41.3	.1414	2
Total					50

Night LAV Readings of Recorded Patient Acuity Categories

WMSN Categories (points)	Mean LAV	Minimum	Maximum	Standard deviation	Cases
Cat III (32-64)	40.6833	40.60	40.8	.0753	6
Cat IV (65-95)	39.2	.000	40.9	7.6920	28
Cat V (96-145)	40.41	39.3	40.9	.5784	14
Cat VI (146-262)	40	39.3	40.7	.9899	2
					50

Table 4

Correlations ( r ) Between Patient Acuity, and Noise Levels

Noise Measurements	APACHE II	WMSN	WMSN Categories
Day LAV	.3539	.4308	.4342
Day MAX	.0102	.1725	.0595
Night LAV	.1122	.0317	.0229
Night MAX	.0556	-.0376	.0117
WMSN	.4308	----	.8742
APACHE II	----	.4308	.4342

Note. All r values have 1-tailed significance of  $p < .001$ ,  $n = 50$

Table 5

ANOVA of Noise Levels by WMSN Categories

Source of Variance	<u>SS</u>	<u>df</u>	<u>MS</u>	<u>F</u>	<u>P</u>
DLAV					
Between groups	2.3629	3	.7876	.8520	.4727
Within groups	42.5221	46	.9244		
NLAV					
Between groups	19.8672	3	6.6224	.1901	.9026
Within group	1602.87	46	34.8452		



#### Question Four

The final question asked was: "What are the characteristics of the patients with the highest acuity levels?" Descriptive statistics were used to analyze WMSN categories compared to patient age and diagnosis (see Table 9). The mean amount of additional equipment per patient by WMSN category was also described statistically (not including cardiac monitor and pulse oxymetry which were used on every ICU patient). As patient acuity and severity of illness increased the potential for additional equipment increased. Table 10 is the average increase of equipment per category. As expected, the WMSN category VI had the highest average additional pieces of equipment, but did not seem to increase room noise (see Table 10). Table 11 shows how a piece of additional equipment could increase the WMSN points, thus, increasing the acuity score. One way analysis of variance was not statistically significant for age and WMSN categories (Table 12).

#### Summary

The four research questions were presented with their findings. The limited range in noise levels and acuity indicated a homogeneous sample. The sample's noise levels ranged from 40.9 dB to 45 dB in the day and 39.3 dB to 40.9 dB at night. Increasing patient acuity levels did not show increasing levels of noise. Noise levels were highest in respiratory and post operative patients but the largest group were cardiac patients. WMSN category VI was the highest acuity and consisted of two patients. Both of these patients had 6 additional pieces of

equipment. Noise levels in category V did not differ from those in category IV.

This study did not indicate an increase in noise levels as acuity increased.

Table 6

Characteristics of Day High/Low Noise by Diagnosis and Gender

Diagnosis	Low Day LAV	High Day LAV	Low Day LMX	High Day LMX
Cardiovascular	27	1	18	10
Respiratory	5	3	5	3
Gastrointestinal				1
Neurological	1			1
Renal	1		1	
Surgery/Postoperative	9	2	5	5
Other	1		1	
<hr/>				
Gender				
Male	27	3	17	13
Female	17	3	13	7

Table 7

Characteristics of Night High /Low Noise By Diagnosis and Gender

Diagnosis	Low Night LAV	High Night LAV	Low Night LMX	High Night LMX
Cardiovascular	28		19	9
Respiratory	8		2	6
Gastrointestinal	1		1	
Neurological	4			1
Renal	5		1	
Surgery/Postoperative	1		2	8
Other	1		1	
<hr/>				
Gender				
Male	30		16	14
Female	20		10	10

Table 8

Frequency of Room Occupancy to High/Low Noise

Room	A	B	C	D	E	F	I	J
Low LAV	7	7	6	4	9	1	4	4
High LAV		1		1			2	1

A to D = Bay beds    E to J = Private beds

Table 9

Characteristics of WMSN Categories by Diagnosis and Gender

Diagnosis	WMSN Cat III	WMSN Cat IV	WMSN Cat V	WMSN Cat VI
Cardiovascular	6	17	5	
Respiratory		6	2	1
Gastrointestinal				1
Neurological		1		
Renal			1	
Surgery/Postoperative		3	6	
Other		1		
<b>Gender</b>				
Male	3	16	9	2
Female	3	12	5	

Table 10

Mean Number of Additional Pieces of Equipment per Patient by WMSNCategories

WMSN	Cat III	Cat IV	Cat V	Cat VI
# of Equipment	4	4	5	6

Table 11

WMSN Points by Equipment Type

Equipment Type	Points per Piece
Oxygen	2
Ventilator	10
A Line/Swan readings (12/day)	2
IV pumps	2

Table 12

ANOVA of WMSN Categories and Patient's Age

WMSN Categories Source of Variance	<u>SS</u>	<u>dF</u>	<u>MS</u>	<u>F</u>	<u>P</u>
Between groups	262	3	87	.9957	.4033
Within groups	4047	46	87		

## Chapter 5

### DISCUSSION, LIMITATIONS, CONCLUSIONS, IMPLICATIONS, AND RECOMMENDATIONS

#### Discussion

This section presents a summary and discussion of the findings reported in Chapter 4. The findings are related to the research cited in the review of literature. Limitations of the study are also discussed. Each of the research questions is addressed separately.

#### Question One

The first question was: "What are the noise levels encountered by adult critical care patients?" In this study day time noise averaged 41.27 dB(A) and nighttime averaged 39.75 dB(A). The daytime range was 40.90 dB to 45 dB and the nighttime range was 39.3 dB to 40.9 dB. The nighttime average was not broad enough to divide into high and low groups. These values are slightly lower than the seminal work done by Woods and Falk (1974) who found noise to range from 50 dB to 70 dB and Hilton (1985) who reported that in the smaller ICUs studied the noise ranged from 34.2 dB to 62.5 dB. In larger ICU/recovery rooms, the sound level remained above 50 dB all of the time and had a maximum range of 68.5 dB. Kotefka (1992) average noise ranged from 43 dB to 66.7 dB. Sound levels in this study are similar to these previously obtained levels. Even though the equipment at the patient's bedside has increased and procedures and practices have changed, noise levels have not increased significantly.

Noise was expected to be higher, especially during the day time.

Equipment was also expected to have more of an effect than it did (i.e. the more

equipment the greater the noise). Neither of these assumptions were statistically supported. It is a possibility that the nursing staff was quicker to turn off alarms during the data collection and that equipment was quieter than twenty years ago.

Since noise above 40 dB is not conducive to rest or sleep, there is still a cause for concern and continued efforts to reduce noise exposure exists.

### Question Two

The second question was: "Is there a relationship between patient acuity level and the level of noise exposure?" No relationship was found because there was no variation in noise levels. The amount of noise did not significantly increase as the patient's acuity increased. A positive correlation was found ( $r = .3539, p = .012$ ) between APACHE II and day LAV but not night LAV ( $r = .1122, p = .438$ ). The WMSN number and category and APACHE II ( $p = .002$ ) were positively correlated. A one-way analysis of variance between patient acuity categories and noise levels did not show statistical significance between groups.

This was the second study which explored noise levels in relationship to acuity scores. Kotefka's (1992) study found a positive relationship between noise and acuity. However, this study's noise ranges were not large enough to show a relationship between noise and patient acuity.

There was an expectation that this study's results would be similar to Kotefka's and that noise would increase with the patient's acuity level. The APACHE II scores indicated a homogeneous population along with the limited noise ranges. A larger variation in noise range or larger sample population would be necessary to achieve statistical results.



### Question Three

The third question was: What are the characteristics of the patients with the highest noise levels?" One myocardial infarct patient fell into the high noise group. Other patients in the high noise group were three respiratory patients, one patient with pneumonia, two in respiratory failure and two surgery postoperative patients, an abdominal aortic aneurysm repair and a gastrointestinal bleed. Night averages remained constant with no variability (range of 39 dB to 40 dB). There was no difference between male and female noise exposure.

It was expected that postoperative patients would have high noise levels at their bedside due to the increased staff interaction immediately following surgery. Did not consider respiratory patients to be at risk for noise exposure. However, nebulizer treatments, chest percussion and vibration, and increased respiratory staff interaction may have contributed to increased noise exposure.

Noise did not effect the APACHE II scores. The limited range of scores were divided between the high and low noise groups.

The other component of this question concerned patient placement: "Is there a differences between bay beds and private rooms in noise exposure?" It was anticipated that the bay beds would be nosier than the private beds. Only two patients from the bay were in the high LAV group compared to three patients in the private rooms. The private rooms were reverse isolation rooms. The isolation blower created its own noise. The patients did not seem to be bothered by the blower; it actually muffled the noise that occurred outside of the room. It

acted as white noise. Once again night noise remained constant. No statistical differences were noted in this ICU between bay and private beds.

#### Question Four

The fourth question was: "What are the characteristics of the patients with the highest acuity levels?". The highest acuity category, category VI had two patients, a hemodynamically unstable gastrointestinal bleed and respiratory failure patient who was ventilator dependent. Category V, the second highest acuity category had many diagnoses: 5 cardiac; 2 respiratory; 1 renal; and 6 postoperative patients. The largest WMSN category was IV. It contained 17 cardiac, 6 respiratory, 1 neurological, 3 postoperative, and 1 other patient diagnosis. Most of the patients fell into Categories IV and V, evenly distributed between male and female. Category IV had the largest sample. Category VI had the most additional pieces of equipment per patient including ventilators and Swan-Ganz monitor. Equipment in use did increase WMSN points, but equipment did not increase the average noise at the patient's bedside.

Once again the expectation was that the highest acuity would have the most equipment and the highest noise. This was not the case. Possible reasons for this include the staff quickly turning off alarms and the possibility that equipment is quieter than twenty years ago. Category VI did have the most equipment per patient, six pieces, but it did not have the highest noise readings. The average noise reading in category VI was 40 dB. Category V had the highest average reading of 40.41 dB.

#### Limitations

The following limitations influenced the results of this study:

1. The sample size may not have been large enough to provide statistically significant information. The power analysis indicated an  $n = 68$  was needed.

However, due to low patient census and time deadline of six weeks, this number was not obtained.

2. The telemetry unit in the facility had closed four beds, thus the ICU admitted patients who would have normally gone to the telemetry unit.

3. The large number of telemetry patients decreased the available beds for higher acuity patients.

4. The myocardial rule out procedure was approximately twenty-four hours long. During this time the patient has serial laboratory and EKGs performed. These patients remain on telemetry and have a higher WMSN score in the first twenty-four hours due to admission procedures, laboratory tests, and EKGs. This influenced the number of patients in Category IV. Data was usually collected within the first twenty-four hours of admission. After twenty-four hours these patients usually became a Category III.

5. The ICU staff informed the researcher that they tried to be quiet during data collection.

### Conclusions

The following conclusions concerning noise and the severely ill were derived as a result of this study:

1. Noise levels at the bedside of critically ill patients in this study were slightly higher than those recommended for undisturbed sleep. The levels were

consistent with those of a noisy office and, therefore, potentially disruptive most of the time.

2. Noise levels at the patient's bedside were approximately the same as reported previously by other researchers even though equipment, procedures and practices have changed during the past 20 years.

3. There was no real difference in noise levels comparing open bay beds to closed rooms.

4. Patient's noise exposure did not increase as acuity increased.

5. Noise remained constant at the bedside regardless of equipment in use.

#### Implications

The physiological/psychological effects of noise were not measured during this study. Several studies have addressed these effects and must be considered when caring for a patient exposed to high levels of noise (i.e. increased heart rate, excretion of norepinephrine and epinephrine). The United States Environmental Protection Agency (1974) and the World Health Organization (1980) state noises above 40 dB during the day and less than 35 dB at night are needed for rest and sleep. Architectural and personnel measures should be taken to reduce noise levels at the bedside to promote physiological as well as psychological health.

Many of the noises found at the bedside can be prevented or reduced. Elander and Hellstrom (1995) demonstrated that a noise awareness program in a pediatric ICU could greatly reduce noise made by staff. The nursing staff attended an hour long presentation on noise intervention. All of the staff attended

the intervention program in working teams. The intervention program had three sections. The first section was a video tape of a child's postoperative period. In it the staff could see the child grimace and cry when subjected to loud noises. The second section was a presentation of decibel levels for various care activities. The third section was a discussion of the problem.

Noise was measured at a cot and in an incubator (pretest) before the intervention program began. The posttest was conducted three months after the last staff group attended the intervention program. There was a significant difference ( $p=0.0001$ ) between decibel levels at the cot and those in the incubator prior to the intervention program. The difference between the cot and the incubator disappeared during the posttest. The incubator's internal environment decibel levels remained relatively constant due to its motor. The intervention program seemed to make the difference in the environmental noise levels at the cot. The equipment, patient acuity, and number of parents and staff were as similar to the pretest as possible. The investigators identified that increasing staff's awareness of noise helped to reduce the noise at the patient's bedside.

While Elander and Hellstrom's (1995) noise intervention program produced positive results in a pediatric setting, it is possible to use the same intervention program with modification in an adult setting

Other reduction measures which can be taken include: decreasing the volume of the telephone ringer, using headphones on televisions and radios, and promptly silencing equipment alarms. Sound absorbent materials should be used whenever possible and doors kept closed when ever possible.

### Recommendations for Further Research

Based on the findings of this study, the following recommendations are made for further research:

1. Expand this study, using a larger sample size.
2. Study the noise exposure levels of patients in various types of units (neurology, surgical, medical).
3. Repeat noise level measurements after a noise intervention program.
4. Monitor noise continuously, throughout a twenty-four hour day to decrease staff awareness of the SLM monitor. This would prevent researcher effect.
5. Survey patients and staff and compare the perceptions of noise on and to the patient.
6. Further study the effects of noise on the patient in the ICU setting. Determine noise levels conducive to sleep and those which are anxiety producing or disruptive.
7. Examine the patient's length of stay in the ICU compared to their noise exposure and severity of illness.
8. Measure staff job performance and the effect noise has upon thought processes and task performance when caring for the severely ill in noisy environment.
9. Explore relationship between physiological variables (heart rate, BP, and cardiac output), noise levels, and acuity levels.

Appendix A  
Data Collection Tool

# DATA COLLECTION TOOL

[illegible]



**Appendix B**  
**APACHE II Severity of Disease Classification System**

# THE APACHE II SEVERITY OF DISEASE CLASSIFICATION SYSTEM

PHYSIOLOGIC VARIABLE	HIGH ABNORMAL RANGE						LOW ABNORMAL RANGE					
	+4	+3	+2	+1	0	+1	+2	+3	+4	+5	+6	+7
TEMPERATURE -- rectal (°C)	≥ 41.0	39.0-40.9		38.5-38.9	38.0-38.4	37.5-37.9	37.0-37.4	36.5-36.9	36.0-36.4	35.5-35.9	35.0-35.4	34.5-34.9
MEAN ARTERIAL PRESSURE -- mm Hg	≥ 160	130-159	110-129		70-109	50-69	30-39	20-29	10-19	0-9	0	0
HEART RATE (ventricular response)	≥ 160	140-179	110-139		70-109	50-69	30-39	20-29	10-19	0-9	0	0
RESPIRATORY RATE -- (non-ventilated or ventilated)	≥ 50	35-49		25-34	12-24	10-11	8-9	6-7	5-6	4-5	3-4	2-3
OXYGENATION: A-aDO <sub>2</sub> or PaO <sub>2</sub> (mm Hg)	≥ 500	350-499	200-349		< 200	< 100	< 50	< 20	< 10	< 5	< 2	< 1
a. FIO <sub>2</sub> ≥ 0.5 record A-aDO <sub>2</sub>												
b. FIO <sub>2</sub> < 0.5 record only PaO <sub>2</sub>												
ARTERIAL pH	≥ 7.7	7.6-7.69		7.5-7.59	7.33-7.49	7.25-7.32	7.15-7.24	7.05-7.14	6.95-7.04	6.85-6.94	6.75-6.84	6.65-6.74
SERUM SODIUM (mMol/L)	≥ 160	140-179	120-159	100-139	80-119	60-89	40-59	20-39	0-19	0	0	0
SERUM POTASSIUM (mMol/L)	≥ 7	6-6.9		5.5-5.9	3.5-3.4	3.3-3.4	3.2-3.3	3.1-3.2	3.0-3.1	2.9-3.0	2.8-2.9	2.7-2.8
SERUM CREATININE (mg/100 ml) [Double point score for acute renal failure]	≥ 3.5	2.3-4	1.5-1.9		0.8-1.4	0.6-0.8	0.4-0.6	0.3-0.4	0.2-0.3	0.1-0.2	0.0-0.1	0.0-0.1
HEMATOCRIT (%)	≥ 60	40-59	30-39	20-29	10-19	0-9	0	0	0	0	0	0
WHITE BLOOD COUNT (total/mm <sup>3</sup> ) (in 1,000s)	≥ 40	30-39	20-29	10-19	0-9	0	0	0	0	0	0	0
GLASGOW COMA SCORE (GCS): Score = 15 minus actual GCS												
TOTAL ACUTE PHYSIOLOGY SCORE (APS): Sum of the 12 individual variable points												
Serum HCO <sub>3</sub> (venous-mMol/L) [Not preferred, use if no ABGs]	≥ 52	41-51.9										

**AGE POINTS:**  
Assign points to age as follows:

AGE (yrs)	Points
≤ 44	0
45-54	2
55-64	3
65-74	5
≥ 75	6

**CHRONIC HEALTH POINTS**  
If the patient has a history of severe organ system insufficiency or is immuno-compromised assign points as follows:

a. for nonoperative or emergency postoperative patients — 5 points  
or  
b. for elective postoperative patients — 2 points

**DEFINITIONS**  
Organ insufficiency or immuno-compromised state must have been evident prior to this hospital admission and conform to the following criteria:

**LIVER:** Biopsy proven cirrhosis and documented portal hypertension; episodes of past upper GI bleeding attributed to portal hypertension; or prior episodes of hepatic failure/encephalopathy/coma.

**RENAL:** Requiring chronic dialysis.

**IMMUNO-COMPROMISED:** The patient has received therapy that suppresses resistance to infection, e.g. immuno-suppression, chemotherapy, radiation, long term or recent high dose steroids, or has a disease that is sufficiently advanced to suppress resistance to infection, e.g. leukemia, lymphoma, AIDS.

**CARDIOVASCULAR:** New York Heart Association Class IV.

**RESPIRATORY:** Chronic restrictive, obstructive, or vascular disease resulting in severe exercise restriction, i.e., unable to climb stairs or perform household duties; or documented chronic hypoxia, hypercapnia, secondary polycythemia, severe pulmonary hypertension (>40mmHg), or respirator dependency.

**APACHE II SCORE**  
Sum of **A** + **B** + **C**

**A** APS points  
**B** Age points  
**C** Chronic Health points

Total APACHE II

FIG. 1. The APACHE II severity of disease classification system.

Appendix C

Workload Management System for Nursing

Addressograph

Enter Date,  
RN Initials,  
and Last Four  
S.S.N ---->

ACTIVITY CODE	SECTION 1 - CRITICAL INDICATORS	POINT VALUES
1	VITAL SIGNS (Manual TPR, BP)	1
2	Vital signs qid or less	2
3	q4h or x 6	3
4	q3h or x 8	4
5	q2h or x 12	8
6	q1h or x 24	2
7	Rectal or axillary temp or apical pulse qid or more	2
8	Respiratory, pedal or popliteal pulse or PMI qid or more	2
9	Tilt test q4h or more	2
10	Post-op, post-partum or post delivery Newborn VS	6
11	MONITORING	
12	Intake and output q4h	2
13	q2h	8
14	Circulation or fundus checks q2h or x 12	2
15	Neuro checks q4h or x 6	3
16	q2h or x 12	6
17	CVP or ICP (manual) q2h or x 12	2
18	Cardiac/apnea/temp/BP monitor (not cumulative)	6
19	Intracranial monitor/oximeter	6
20	A-line or ICP monitor or Swan Ganz set-up	4
21	A-line or ICP monitor reading q2h or x 12	2
22	Swan Ganz PAP/PA wedge reading q4h or x 6	2
23	q2h or x 12	4
24	Cardiac output tid or x 3	2
25	ACTIVITIES OF DAILY LIVING	
26	Care - age 5 or less - (Infant/toddler)	6
27	Care - age 6 or more - Self/Minimal	2
28	- Assisted	6
29	- Complete	14
30	- Total	32
31	Extra linen change & partial bath x 2 per shift	4
32	Turning frame - 2 staff members - q2h	14
33	Peds recreation/observation - age 0-12	8
34	FEEDING	
35	Spoon feed meals - age 6 or more - x 3	6
36	- age 5 or less - x 3	10
37	Infant/neonate bottle x 1 feeding	2
38	q4h or x 6	12
39	q3h or x 8	16
40	Tube feed bolus q4h or x 6	5
41	q3h or x 8	8
42	q2h or x 12	10
43	Tube feed - Adult/child/neonate (continuous)	2
44	SUBTOTAL A POINT VALUE	

HQ JMMC-SA Form 3038 SEP 89 (Test)

(OPR: WHMC/SGHNI)

Expires: 31 Dec 89

## PATIENT ACUITY WORKSHEET (GENERAL)

Enter Date, RN Initials,  
and Last four S.S.N ---->

ACTIVITY CODE	SECTION 1 - CRITICAL INDICATORS (continued)	POINT VALUES
40	IV THERAPY	
41	Start IV	2
42	Change bottle/bag/voluntrol bid or less	4
43	tid or qid	6
44	x 5 or more	8
45	Heperin lock or Broviac q4h or x 6	4
46	IV medication q4h or x 3	2
47	q4h or x 4	3
48	q4h or x 6	4
49	Blood products per unit	2
50	Infusion controller/pump (each)	2
51	TREATMENTS/PROCEDURES/MEDICATIONS	
52	Insert NG	2
53	Pre-op prep/enema/Ace uraps/support hose	2
54	Catheterization - Foley/straight	2
55	Tube care (Exclude trach)	2
56	Dressing - simple 5 - 7 mins x 2	2
57	- complex 30 mins x 1	4
58	Lab tests performed/collected on the unit x 3	2
59	Do EKG	2
60	Venipuncture, arterial puncture x 2	2
61	Medications - exclude IV- 3-11 trips q3h-q4h	2
62	Medications - exclude IV- 12 trips or more q2h	4
63	Irrigations or instillations x 4 or less	2
64	Restraints, 2 point, 4 point, Posey	2
65	Assist OOB chair/gurney x 3	2
66	Assist to ambulate x 1	2
67	Infant circumcision or phototherapy	2
68	Isolation mask, gown and gloves x 8	2
69	Chest tube insertion or lumbar puncture (assist)	4
70	Thoracentesis or paracentesis (assist)	4
71	Range of motion exercises x 3	4
72	New admission - assessment and orientation	12
73	Transfer - In-house (receiving unit only)	4
74	Accompany patient off unit 15 minutes	2
75	30 minutes	4
76	45 minutes	6
77	Other activities requiring 15 minutes	2
78	requiring 30 minutes	4
79	requiring 45 minutes	6
80	Each hour requiring continuous staff attendance	8
81	SUBTOTAL B POINT VALUE	

(continued on other side)

# PATIENT ACUITY WORKSHEET (GENERAL)

COMMENTS

Enter Date, AM Initials, and Last four S.S.N. ----&gt;

ACUITY CODE	SECTION 1 - CRITICAL INDICATORS (continued)	POINT VALUES
79	RESPIRATORY THERAPY	
80	Oxygen therapy or oxymeter	2
81	Incentive spirometer or C & DB q4h or x 6	2
82	IPPB or Maximal bid or x 2	2
83	q4h or x 4	4
84	q4h or x 6	6
85	Group tent or mist tent	8
86	Chest pulmonary therapy bid or x 2	2
87	q4h or x 4	4
88	q4h or x 6	6
89	Suctioning q4h or x 6	2
90	q4h or x 12	4
91	Ventilator	10
92	Tracheostomy care x 3	4
93	TEACHING	
94	Teaching - Group - per hour	2
95	Teaching - Individual - per 30 minutes	4
96	EMOTIONAL SUPPORT	
97	Patient/family support per 30 minutes	4
98	Lifestyle modification per 30 minutes	4
99	Sensory deprivation - blind, deaf, retarded, etc.	6
100	Maximum points for emotional support	10
101	CONTINUOUS	
102	Patient requiring 1:1 coverage all shifts	96
103	Patient requiring > 1:1 coverage all shifts	146
SUBTOTAL A POINT VALUE		
SUBTOTAL B POINT VALUE		
TOTAL POINT VALUE		
CATEGORY		

## SECTION II - ADDITIONAL DATA ACUITY TABLE

Category 0-	0 points
Category 1-	1- 12 points
Category 11-	13- 31 points
Category 111-	32- 63 points
Category 1111-	64- 95 points
Category 11111-	96- 145 points
Category 111111-	146- 262 points

Ass  
Minim  
Moder  
Acute  
Chronic  
Criti

### TYPE OF PATIENT

Med/Surg	
ICU	
WICU	
Nursery	
Antepartum/Postpartum	
Pediatric	
Psychiatric	

Check the appropriate box.

## Appendix D

### Letter of Exemption From the Institutional Review Board

UNIVERSITY OF MARYLAND  
AT BALTIMORE  
INSTITUTIONAL REVIEW BOARD

655 W. Baltimore St.  
BRB 14-016

Baltimore, MD  
21201-1559

MEMORANDUM

TO: Deborah Wright Shpritz, Principal Investigator  
Caryl J. Moulder, Master's Candidate

FROM: UMAB Institutional Review Board (IRB)  
Assurance Number M1174-01NR

RE: "Patient Acuity & Noise in the Intensive Care Unit"  
(Exemption No. DWS-109601)

DATE: October 3, 1996

---

The above-referenced project has been reviewed and determined to be exempt from the IRB approval process according to the Department of Health and Human Services Office for Protection from Research Risks Code of Federal Regulations 45 CF406420-049401R 46.101.b (4).

If the protocol is altered in any way, it must be reviewed by the IRB.

Please keep a copy of this letter for future reference. If you have any questions, please do not hesitate to contact the IRB Office at (410) 706-5037.



Paul Fishman, MD, Chairman  
Institutional Review Board

CC: IRB Exemption File

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